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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

CUBIST PHARMACEUTICALS LLC,

Plaintiff,

v.

CIPLA USA, INC. and CIPLA LIMITED,

Defendants.

Civil Action No. _____

**COMPLAINT FOR PATENT
INFRINGEMENT**

(Filed Electronically)

Plaintiff Cubist Pharmaceuticals LLC (“Cubist” or “Plaintiff”) by its attorneys, for their complaint against Cipla USA, Inc. (“Cipla USA”) and Cipla Limited (collectively, “Cipla” or “Defendants”), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent No. 9,138,456 (the “456 patent”) under the laws of the United States, 35 U.S.C. § 100, *et seq.* This action arises from Cipla Limited’s filing of Abbreviated New Drug Application (“ANDA”) No. 213027 (“the Cipla ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to commercially market a generic version of Plaintiff’s CUBICIN RF® drug product (“Cipla’s Proposed ANDA Product”).

THE PARTIES

2. Cubist is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at Weystrasse 20, 6000 Lucerne 6, Switzerland.

3. Upon information and belief, Cipla USA is a Delaware corporation having a principal place of business at 10 Independence Boulevard, Warren, Somerset County, New Jersey 07059. Upon information and belief, Cipla USA has established commercial offices in Warren, New Jersey. Upon further information and belief, Cipla USA is the United States wholly-owned subsidiary of Cipla Limited.

4. Upon information and belief, Cipla Limited is an Indian corporation having a principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India.

THE PATENT-IN-SUIT

5. On September 22, 2015, the United States Patent and Trademark Office (“USPTO”) duly and lawfully issued the ’456 patent, which is owned by Cubist, entitled “Lipopetide Compositions And Related Methods.” A copy of the ’456 patent is attached as Exhibit A.

THE CUBICIN RF® DRUG PRODUCT

6. Cubist holds approved New Drug Application (“NDA”) No. 021572 for daptomycin for injection, which is prescribed and sold under the trademark CUBICIN RF®. CUBICIN RF® is indicated for the treatment of complicated skin and skin structure infections and *Staphylococcus aureus* bloodstream infections in adult and pediatric patients.

7. The claims of the ’456 patent cover, *inter alia*, solid pharmaceutical daptomycin compositions.

8. Pursuant to 21 U.S.C. § 335(b)(1), and attendant FDA regulations, the ’456 patent is listed in the FDA publication “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), with respect to CUBICIN RF®.

SUBJECT MATTER JURISDICTION

9. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

PERSONAL JURISDICTION AND VENUE OVER CIPLA USA

10. This Court has personal jurisdiction over Cipla USA because Cipla USA has purposefully availed itself of the rights and benefits of New Jersey law by engaging in

systematic and continuous contacts with the State of New Jersey. Upon information and belief, Cipla USA regularly and continuously transacts business within New Jersey, including by establishing a principal place of business in New Jersey and by selling pharmaceutical products in New Jersey. Upon information and belief, Cipla USA derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

11. Upon information and belief, Cipla USA has continuously placed its products into the stream of commerce for distribution and consumption in the State of New Jersey and throughout the United States, and thus has engaged in the regular conduct of business within this Judicial District.

12. The Cipla ANDA identifies Cipla USA as an entity that would market Cipla's Proposed ANDA Product in the United States. Upon information and belief, Cipla USA agreed to market such product and intends a future course of conduct that includes acts of patent infringement in New Jersey. Upon information and belief, Cipla USA's acts have led and will lead to foreseeable harm and injury to Plaintiff in New Jersey. Upon information and belief, following approval of the Cipla ANDA, Cipla USA will make, use, import, sell, and/or offer for sale the Cipla's Proposed ANDA Product in the United States, including in New Jersey. Upon information and belief, Cipla USA will conduct such acts from its regular and established place of business in Warren, Somerset Country, New Jersey.

13. Upon information and belief, Cipla USA has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

14. Cipla USA has previously been sued in this Judicial District and has availed itself of courts in New Jersey through the assertion of counterclaims in suits brought in New Jersey, including *Valeant Pharmaceuticals North America LLC et al v. Cipla Limited and Cipla USA, Inc.*, Civil Action No. 3-18-cv-14225 (D.N.J.) (not contesting personal jurisdiction or venue and asserting counterclaims) and *AstraZeneca AB et al v. Cipla Limited and Cipla USA, Inc.*, Civil Action No. 1-16-cv-09583 (D.N.J.) (not contesting personal jurisdiction or venue and asserting counterclaims) and has consented to the jurisdiction of this Court in these cases and others, including *Merck, Sharp & Dohme Corp. v. Cipla USA, Inc.*, Civil Action No. 1-13-cv-04017 (D.N.J.) (withdrew motion to dismiss following court's order on jurisdictional discovery and consented to personal jurisdiction).

15. Venue is proper for Cipla USA under 28 U.S.C. § 1400(b) because Cipla USA has a regular and established place of business in Warren, Somerset Country, New Jersey, and has or will commit acts of infringement in New Jersey, as set forth in paragraphs 11-12 and 29-33.

PERSONAL JURISDICTION AND VENUE OVER CIPLA LIMITED

16. This Court has personal jurisdiction over Cipla Limited because, *inter alia*, Cipla Limited has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiff in New Jersey. For example, on information and belief, following approval of Cipla's Proposed ANDA Product, Cipla Limited will make, use, import, sell, and/or offer for sale the Cipla's Proposed ANDA Product in the United States, including in New Jersey.

17. This Court also has personal jurisdiction over Cipla Limited because, *inter alia*, this action arises from actions of Cipla Limited directed toward New Jersey. For example, Cipla Limited's counsel sent a letter dated April 15, 2019 directed to Cubist's offices in New Jersey stating that Cipla Limited had submitted ANDA No. 213027 seeking approval to commercially manufacture, use, import, offer for sale, and sell Cipla's Proposed ANDA Product prior to the expiration of the '456 patent. If Cipla Limited succeeds in obtaining FDA approval, it would sell Cipla's Proposed ANDA Product in New Jersey and other states, causing injury to Plaintiff in New Jersey.

18. The Court also has personal jurisdiction over Cipla Limited because Cipla Limited has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, Cipla Limited regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. On information and belief, Cipla Limited derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

19. On information and belief, Cipla Limited has continuously placed its products into the stream of commerce for distribution and consumption in the State of New Jersey and throughout the United States, and thus has engaged in the regular conduct of business within this Judicial District.

20. On information and belief, Cipla Limited derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this Judicial District.

21. On information and belief, Cipla Limited has previously invoked, stipulated, and/or consented to personal jurisdiction in this Judicial District in numerous prior patent cases.

22. Cipla Limited has previously been sued in this Judicial District and has availed itself of courts in New Jersey through the assertion of counterclaims in suits brought in New Jersey, including *Celgene Corp. v. Cipla Ltd.*, Civil Action No. 2-18-cv-08964 (D.N.J.) (not contesting personal jurisdiction or venue and asserting counterclaims); *Celgene Corp. v. Cipla Limited*, Civil Action No. 3-18-cv-11262 (D.N.J.) (not contesting personal jurisdiction or venue and asserting counterclaims); *Valeant Pharmaceuticals North America LLC et al v. Cipla Limited and Cipla USA, Inc.*, Civil Action No. 3-18-cv-14225 (D.N.J.) (not contesting personal jurisdiction or venue and asserting counterclaims); *AstraZeneca AB et al v. Cipla Limited and Cipla USA, Inc.*, Civil Action No. 1-16-cv-09583 (D.N.J.) (not contesting personal jurisdiction or venue and asserting counterclaims).

23. Venue is proper for Cipla Limited under 28 U.S.C. §§ 1391(c)-(d) and 1400(b). Cipla Limited is a foreign corporation and venue is proper in any judicial district having personal jurisdiction, including this Judicial District. Additionally, Cipla Limited operates in the United States through its subsidiary, Cipla USA, which has a regular and established place of business in Warren, Somerset County, New Jersey, and Cipla Limited has or will commit acts of infringement in New Jersey, as set forth in paragraphs 24-33.

CIPLA LIMITED'S INFRINGING ANDA SUBMISSION

24. On or about April 16, 2019, Cubist received from Cipla Limited's counsel a letter dated April 15, 2019, stating that Cipla Limited had submitted the Cipla ANDA to the FDA seeking approval to market Cipla's Proposed ANDA Product before the expiration of the

'456 patent. Cipla's Proposed ANDA Product is intended to be a generic version of CUBICIN RF®.

25. The April 15 letter notified Plaintiff that the Cipla ANDA includes a certification pursuant to § 505(j)(2)(B)(i)-(iv) of the Federal Food, Drug and Cosmetic Act ("Cipla Limited's Paragraph IV Certification"), that in Cipla's opinion, the '456 patent is "invalid, unenforceable, or not infringed, in connection with Cipla's ANDA seeking approval for Daptomycin for Injection, 500 mg per vial."

26. Cipla Limited's Paragraph IV Certification alleges that Cipla's Proposed ANDA Product does not infringe certain claims of the '456 patent. Notwithstanding these allegations, on information and belief, discovery and/or testing will show that Cipla's Proposed ANDA Product infringes the '456 patent.

27. Upon information and belief, Cipla intends to market Cipla's Proposed ANDA Product in the United States.

28. This action is being commenced before the expiration of 45 days from the date Cubist received Cipla Limited's April 15 Letter.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 9,138,456 BY DEFENDANTS

29. Plaintiff repeats and realleges paragraphs 1-28 above as if fully set forth herein.

30. By filing the Cipla ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Cipla's Proposed ANDA Product before the expiration of the '456 patent, Cipla Limited committed an act of infringement under 35 U.S.C. § 271(e)(2).

31. Upon information and belief, discovery and/or testing will show that if Cipla commercially makes, uses, offers to sell, or sells Cipla's Proposed ANDA Product within the United States, including in New Jersey, or imports Cipla's Proposed ANDA Product into the United States, including in New Jersey, or induces or contributes to any such conduct during the term of the '456 patent, it would further infringe at least claims 1-2 and 7-11 of the '456 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). In addition, Cipla Limited's Paragraph IV Certification does not dispute that it infringes at least one claim of the '456 patent.

32. Cipla has had knowledge of the '456 patent since at least the date it submitted the Cipla ANDA.

33. Plaintiff will be irreparably harmed if Cipla is not enjoined from infringing the '456 patent. Plaintiff does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

A. A Judgment that Cipla has infringed one or more claims of the '456 patent by filing ANDA No. 213027;

B. A Judgment that Cipla has infringed, and that Cipla's making, using, selling, offering to sell, or importing Cipla's Proposed ANDA Product would constitute infringement of one or more claims of the '456 patent, and/or induce or contribute to the infringement of, one or more claims of the '456 patent pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

C. A permanent injunction restraining and enjoining Cipla, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or

importation into the United States, of Cipla's Proposed ANDA Product until after the expiration of the '456 patent, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

D. An Order that the effective date of any approval of ANDA No. 213027 relating to Cipla's Proposed ANDA Product be a date that is not earlier than the expiration date of the '456 patent plus any other regulatory exclusivity to which Plaintiff is or becomes entitled; and

E. Such other and further relief as the Court may deem just and proper.

Dated: May 24, 2019

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2 and 201.1(d)

I certify that, to the best of my knowledge, the matter in controversy in this action is not the subject of any other action pending in any court and is not the subject of any pending arbitration or administrative proceeding.

I certify that Plaintiff's Complaint seeks non-monetary relief, and that this case is therefore exempt from compulsory arbitration.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on May 24, 2019 in Parsippany New Jersey.

By: /s/ Elizabeth J. Sher

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